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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/955,572	10/22/97	KWON	B IND4-DI1B

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EXAMINER	
LANDSMAN, R	
ART UNIT	PAPER NUMBER
1646	32
DATE MAILED: 04/27/00	

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/955,572

Applicant(s)

KWON, BYOUNG S.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,6,24 and 26-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,6,24 and 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____

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DETAILED ACTION

- A. The Sequence Listing, filed 2/2/00, has been entered into the record.
- B. All 35 U.S.C. statutes not found in this Office Action can be found, cited in full, in a previous Office Action.

1. Oath/Declaration

- A. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: in the remarks to the rejection of 102(a) in view of Alderson et al. Applicants claim priority to 08/122,976, however, this serial number is not referred to in the specification.

2. Claim Rejections - 35 USC § 112, first paragraph

- A. The previous Action states that claim 26 is rejected since there is no guidance or examples pertaining to the use of an H4-1BB polypeptide are disclosed that would provide a reasonable expectation of success using the claimed invention to treat a disease or clinical condition. Applicants argue that deletion of the term "pharmaceutical" in claim 26 would not raise the points at issue. However, the previous Action argues that the function of the H4-1BB protein is not known, regardless of its use in a pharmaceutical composition. For this reason, the rejection of claim 26 is maintained for the reasons set forth in the previous Office Action. See especially page 5, last paragraph. The Action states "it is not known how H4-1BB affects T-cells or what T-cell-associated disease(s) are dependent on H4-1BB activity." And that there is a "lack of information" about H4-1BB. In summary, there is no guidance or

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working examples of how to use this protein in the treatment of any T-cell-associated disease. Furthermore, it is not predictable to one of ordinary skill in the art how to use this protein. Therefore, there is a lack of written description of how to use this protein which leads to undue experimentation.

B. Claims 5 and 26-31 encompass subject matter not disclosed in the specification. These claims recite a protein produced by expressing DNA encoding a protein of SEQ ID NO:2. However, the wording of these claims read on a gene, or an entire chromosome and a review of the specification indicates that elements which are not particularly described, including regulatory elements and untranslated regions, are essential to the function of the claimed invention. The art indicates that the structure of genes with naturally occurring regulatory elements and untranslated regions is empirically determined. For example, the structural elements of a gene mediating the expression of a particular protein in the liver may be different than the structural elements of the gene mediating the expression of the same protein in the brain. Therefore, the structure of these elements essential to the function of the claim are not conventional in the art. There is no actual reduction to practice of the claimed invention, clear depiction of the claimed invention in the drawings, or complete detailed description of the structure.

Considering all disclosed distinguishing identifying characteristics, there is a disclosure of partial structure as well as the function of the gene as coding for a G protein-coupled receptor (SEQ ID NO:2). However, there is no known or disclosed correlation between this function and the structure of the non-described regulatory elements and untranslated region of the gene. Furthermore, there is no additional disclosure of physical and/or chemical properties. Weighing all factors in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the Applicant was in possession of the genus of genes which encodes SEQ ID NO:2. The claim is drawn to a genus, i.e., any

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gene which encodes SEQ ID NO:2. For the reasons given above these claims are rejected as lacking adequate written description.

3. Claim Rejections - 35 USC § 112, second paragraph

A. The previous Action states that claims 5, 24 and 26-30 are rejected since they are indefinite because it is not clear what, besides a fragment of SEQ ID NO:2, must be present in an H4-1BB receptor protein or soluble peptide. Applicants argue that the metes and bounds of these claims would be readily recognizable and understood by the art worker in possession of Applicants' specification. This rejection has been withdrawn in view of Applicants' arguments.

The rejection of claims 24 and 27, with regard to being unclear if the fragment is a fragment of SEQ ID NO:2, has been withdrawn in view of Applicants' amendments to the claims in which the phrase "of the extracellular domain" has been added.

The previous Action states that claims 28 and 30 are indefinite because the hybridization conditions are not clear and no hybridization conditions are given. Applicants have amended the claims to include the phrase "specifically hybridizes," however, no the term "specifically" is vague and Applicants provide no hybridization conditions. For this reason, the rejection of claims 28 and 30 are maintained.

4. Claim Rejections - 35 USC § 102

A. All claims rejected under 35 USC 102 have been withdrawn in view of Applicants' arguments.

5. Claim Rejections - 35 USC § 103

A. All claims rejected under 35 USC 102 have been withdrawn in view of Applicants' arguments.

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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
April 24, 2000

Gary L. Kunz
GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200